Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Breast Mass	4 (1.0)	3 (0.8)	5 (1.3)	2 (0.5)
External Injury Not Related To Breast Implants	1 (0.3)			1 (0.3)
Inflammation	1 (0.3)	1 (0.3)		
Patient Dissatisfied With Appearance	2 (0.5)		4 (1.0)	
Recurrent Breast Cancer		1 (0.3)		
Surgical Complications Related To Technique	1 (0.3)	3 (0.8)		
Other	1 (0.3)	3 (0.8)	5 (1.3)	2 (0.5)
Abnormal Mammogram			1 (0.3)	1 (0.3)
Capsule Tear	1 (0.3)			
False Positive For Rupture On Mammogram				1 (0.3)
Muscle Spasm		2 (0.5)	2 (0.5)	
Nipple Related Unplanned			1 (0.3)	
Siliconoma				1 (0 3)
Skin Lesion			1 (0.3)	
Symmastia		1 (0.3)		
Any Complication Excluding Cosmetic	61 (15.8)	58 (15.1)	59 (15.4)	21 (5.6)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS Creation Date, Time: 29JUL04 12:21

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Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
II. Cosmetic Complication				
Asymmetry	1 (0.3)	2 (0.5)	1 (0.3)	1 (0.3)
Hypertrophic Scarring	9 (2.3)	6 (1.6)	12 (3.1)	3 (0.8)
Ptosis	2 (0.5)	3 (0.8)	6 (1.6)	4 (1.1)
Size Change - Patient Request	3 (0.8)		6 (1.6)	2 (0.5)
Wrinkling	5 (1.3)	3 (0.8)	1 (0.3)	
Any Cosmetic Complication	20 (5.2)	14 (3.6)	25 (6.5)	9 (2.4)
III. Reoperations				
Explant Regardless of Replacement	7 (1.8)	9 (2.3)	11 (2.9)	10 (2.7)
Explant with Replacement with Study Device	4 (1.0)	8 (2.1)	6 (1.6)	3 (0.8)
Explant without Replacement	3 (0.8)	1 (0.3)	5 (1.3)	7 (1.9)
Other Reoperations	19 (4.9)	24 (6.3)	13 (3.4)	13 (3.5)
Biopsy	3 (0.8)	2 (0.5)	1 (0.3)	2 (0.5)
Capsulectomy	3 (0.8)	9 (2.3)	1 (0.3)	5 (1.3)
Incision and Drainage	6 (1.6)			
Mastopexy		4 (1.0)		1 (0.3)
Capsulotomy	3 (0.8)	8 (2.1)	2 (0.5)	1 (0.3)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS Creation Date, Time: 29JUL04 12:21

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Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Implant Reposition		4 (1.0)	4 (1.0)	2 (0.5)
Scar Revision	1 (0.3)	4 (1.0)	3 (0.8)	1 (0.3)
Skin Adjustment	2 (0.5)	6 (1.6)	3 (0.8)	
Capsulorrhaphy	2 (0.5)	2 (0.5)	2 (0.5)	
Nipple Related Procedure (unplanned)				1 (0.3)
Revision Of Wound Closure	2 (0.5)			
Other		2 (0.5)	3 (0.8)	2 (0.5)
Excision Of Skin Lesion		2 (0.5)		
Exploration Right Breast With Evacuation Of Hematoma			1 (0.3)	
Kenalog Injection			2 (0.5)	
Needle Aspiration				1 (0.3)
Open Incision To Rule Out Implant Rupture				1 (0.3)
Any Reoperation	26 (6.7)	25 (6.5)	21 (5.5)	16 (4.3)
Total Implants Assessed	386	384	384	374

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS Creation Date, Time: 29JUL04 12:21

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Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)
OVERALL IMPLANTS

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	306	257	255	116
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	61 (3.2)	71 (3.8)	59 (3.1)	28 (1.5)
Baker III Capsular Contracture	54 (2.8)	63 (3.3)	53 (2.8)	23 (1.2)
Baker IV Capsular Contracture	7 (0.4)	11 (0.6)	10 (0.5)	7 (0.4)
Breast pain	13 (0.7)	3 (0.2)	10 (0.5)	3 (0.2)
Breast Sensation Changes	14 (0.7)	18 (1.0)	13 (0.7)	3 (0.2)
Delayed Wound Healing	7 (0.4)			
Extrusion	4 (0.2)	2 (0.1)		
Granuloma	3 (0.2)	1 (0.1)		
Hematoma	20 (1.1)	1 (0.1)	3 (0.2)	1 (0.1)
Infection	18 (0.9)	3 (0.2)	4 (0.2)	
Lymphadenopathy	1 (0.1)			1 (0.1)
Necrosis	1 (0.1)			3 (0.2)
New Diagnosis of Breast Cancer		1 (0.1)		
Nipple Sensation Changes	65 (3.4)	68 (3.6)	59 (3.1)	21 (1.1)
Implant Malposition/Displacement	7 (0.4)	6 (0.3)	6 (0.3)	
Rupture			11 (0.6)	5 (0.3)

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Note 3: Implant counts exclude events where breast side = N/A.

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Table 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)
OVERALL IMPLANTS

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Seroma	20 (1.1)		2 (0.1)	
Lactation Difficulties			2 (0.1)	1 (0.1)
Breast Mass	6 (0.3)	8 (0.4)	18 (1.0)	5 (0.3)
Breast Rash	5 (0.3)		1 (0.1)	
External Injury Not Related To Breast Implants	5 (0.3)	2 (0.1)		3 (0.2)
Inflammation	3 (0.2)	2 (0.1)		
Metastatic Disease				2 (0.1)
Patient Dissatisfied With Appearance	2 (0.1)	4 (0.2)	6 (0.3)	
Placement Damage	4 (0.2)			
Recurrent Breast Cancer	2 (0.1)	4 (0.2)	3 (0.2)	
Surgical Complications Related To Technique	11 (0.6)	7 (0.4)	1 (0.1)	
Suture Reaction	4 (0.2)	2 (0.1)		
Other	11 (0.6)	9 (0.5)	11 (0.6)	8 (0.4)
Abnormal Mammogram			1 (0.1)	1 (0.1)
Capsular Contracture Secondary To Radiation Therapy	1 (0.1)	1 (0.1)	1 (0.1)	
Capsule Tear	1 (0.1)			

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS Creation Date, Time. 29JUL04 12:21

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Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: Implant counts exclude events where breast side = N/A.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)
OVERALL IMPLANTS

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Cellulitis	1 (0.1)			
Distortion Of Breast Shape Not Related To Capsular Contracture	1 (0.1)	2 (0.1)	1 (0.1)	1 (0.1)
Explanted Due To Right Side Being Removed				2 (0.1)
False Positive For Rupture On Mammogram				1 (0.1)
Lack Of Projection			1 (0.1)	
Mondor's Disease	3 (0.2)			
Muscle Spasm	1 (0.1)	3 (0.2)	2 (0.1)	
Nipple Complications	1 (0.1)		2 (0.1)	
Nipple Related Unplanned			1 (0.1)	
Occasional Burning Discomfort Of Skin.				2 (0.1)
Pain - Sternum And Under Left Arm Intermittent	1 (0.1)			
Pt Requests Removal Due To Personal Reasons		2 (0.1)		
Siliconoma				1 (0.1)

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OVERALL IMPLANTS

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Skin Lesion	1 (0.1)		1 (0.1)	
Soft Mass Left Costal Margin			1 (0.1)	
Stitch Abscess				1 (0.1)
Symmastia		1 (0.1)		
Any Complication Excluding Cosmetic	238 (12.6)	190 (10.0)	180 (9.6)	79 (4.3)
II. Cosmetic Complication				
Asymmetry	12 (0.6)	14 (0.7)	5 (0.3)	5 (0.3)
Hypertrophic Scarring	39 (2.1)	40 (2.1)	44 (2.3)	12 (0.7)
Ptosis	9 (0.5)	8 (0.4)	26 (1.4)	15 (0.8)
Size Change - Patient Request	17 (0.9)	11 (0.6)	11 (0.6)	10 (0.5)
Size Change - Physician Assessment only	5 (0.3)	5 (0.3)	2 (0.1)	
Wrinkling	11 (0.6)	8 (0.4)	4 (0.2)	1 (0.1)
Any Cosmetic Complication	87 (4.6)	81 (4.3)	88 (4.7)	42 (2.3)
III. Reoperations				
Explant Regardless of Replacement	26 (1.4)	34 (1.8)	32 (1.7)	25 (1 4)
Explant with Replacement with Study Device	18 (0.9)	25 (1.3)	18 (1.0)	7 (0.4)

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Note 3: Implant counts exclude events where breast side = N/A.

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Table 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)
OVERALL IMPLANTS

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Explant without Replacement	8 (0.4)	9 (0.5)	14 (0.7)	18 (1.0)
Other Reoperations	78 (4.1)	69 (3.6)	58 (3.1)	30 (1.6)
Biopsy	9 (0.5)	6 (0.3)	5 (0.3)	2 (0.1)
Capsulectomy	16 (0.8)	21 (1.1)	15 (0.8)	10 (0.5)
Incision and Drainage	18 (0.9)	1 (0.1)	1 (0.1)	1 (0.1)
Mastopexy	1 (0.1)	4 (0.2)	4 (0.2)	4 (0.2)
Capsulotomy	12 (0.6)	20 (1.1)	9 (0.5)	4 (0.2)
Implant Reposition	8 (0.4)	10 (0.5)	11 (0.6)	2 (0.1)
Scar Revision	4 (0.2)	10 (0.5)	16 (0.9)	4 (0.2)
Skin Adjustment	11 (0.6)	12 (0.6)	7 (0.4)	3 (0.2)
Capsulorrhaphy	7 (0.4)	3 (0.2)	2 (0.1)	
Implant Pocket Revision		4 (0.2)	4 (0.2)	
Nipple Related Procedure (unplanned)	1 (0.1)	2 (0.1)		1 (0.1)
Revision Of Wound Closure	5 (0.3)	1 (0.1)		
Other	3 (0.2)	3 (0.2)	7 (0.4)	3 (0.2)
Create Inframmary Fold	1 (0.1)	1 (0.1)		
Excise Breast Mass			1 (0.1)	1 (0.1)
Excision Of Skin Lesion		2 (0.1)		

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OVERALL IMPLANTS

	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
Type of Complication or Reoperation	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Exploration Right Breast With Evacuation Of Hematoma			1 (0.1)	
Flap Coverage Of Expander			1 (0.1)	
Kenalog Injection			2 (0.1)	
Needle Aspiration				1 (0.1)
Open Incision To Rule Out Implant Rupture				1 (0.1)
Removal Of Nodule On Chest Wall	2 (0.1)			
Revision Of Breast / External To Pocket			2 (0.1)	
Any Reoperation	98 (5.2)	86 (4.5)	77 (4.1)	42 (2.3)
Total Implants Assessed	1896	1891	1881	1841

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